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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,314	02/06/2002	Michael T. Trese	TMT-10902/04	8834

7590 03/24/2005

Avery N. Goldstein
Gifford, Krass, Groh, Sprinkle,
Anderson & Citkowski, P.C.
280 N. Old Woodward Avenue, Suite 400
Birmingham, MI 48009-5394

EXAMINER	
DESANTO, MATTHEW F	
ART UNIT	**PAPER NUMBER**
3763	

DATE MAILED: 03/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,314	TRESE ET AL.	
	Examiner	Art Unit	
	Matthew F DeSanto	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10, 13- 21, and 24-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10,13-21 and 24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☒ Interview Summary (PTO-413) Paper No(s)/Mail Date. *3/8/05*.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-7, 9, 10, 13-18, 20, and 21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over by Trese et al. (Ophthalmology, Volume 105, Issue 9, 1 September 1998, pages 1617-1620).

Trese et al. discloses the delivery of autologous human plasmin into a vitreous body of an eye and then incubating the eye. Trese et al. discloses using 0.4 IU, but fails to disclose a size of dose smaller then 0.4 IU.

AT the time of the invention it would have been obvious for one of ordinary skill in the art to modify the teachings of Trese et al. because it is well known in the medical field art to vary the does size that will be injected into a patient, since medication usually depends on the size of the patient as well as the area in which the injection will occur. This concept is well known in the research art and can be seen in the previous cited prior art (Entire reference).

3. Claims 8, 19, 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Trese et al. (Ophthalmology, Volume 105, Issue 9, 1 September 1998, pages 1617-1620) as applied to

the claims above, and further in view of Trese et al. (American Academy of Ophthalmology, ISSN 1607-1610).

Trese et al. (Ophthalmology) discloses the claimed invention but fails to specifically point out the use of a plasmin inhibitor and the actual size of the needle being used to remove the liquefaction that occurred in the eye.

Trese et al. (American Academy of Ophthalmology) discloses the use of a plasmin for the liquefaction of the eye as well as the use of small gauge needles for sucking the material out of the eye (page 1610 2nd Column, 1st paragraph) and the use of a plasmin inhibitor to reduce to the activity of the plasmin that was injection into the eye (surgical techniques).

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the teachings of Trese et al. with Trese et al. because Trese et al. (American) provides further explanation as to why those steps are necessary. Trese et al. (American) also discloses the level of skill in the medical art since it is well known in the art to perform these steps.

Response to Amendment

4. The declaration under 37 CFR 1.132 filed on 5/24/04 is insufficient to overcome the rejection of claims 1-21, and 24 based upon Trese et al. as set forth in the last Office action because: the examiner still believes that it would have been obvious to change the concentration and size of the plasmin that is being injected into the eye.

Response to Arguments

5. Applicant's arguments filed on 1/13/05 have been fully considered but they are not persuasive.

6. With regards to streptokinase-plasminogen being produced in the Trese et al. prior art, and the arguments drawn to this rejection, the examiner disagrees because one of ordinary skill in the art would interpret the article to produce autologous plasmin since this is what is stated.

7. The examiner still keeps the rejections because the applicant is trying to get a patent on the method of liquefying the eye with a plasmin. This is taught in the prior art references.

8. The examiner is basing the rejections that it would have been obvious to change the size and concentration of the plasmin that would be injected in an eye. It is well known in the art to vary the concentration and size of a dose through routine and well-known experimentation procedures to see whether vitreous liquefaction of the eye will occur. The examiner determines that it would be obvious to vary the concentration and volume of a dose in an experiment, especially when performing research so that a conclusion can be reached with regards to the dose and concentration. Thus the examiner determines that normal experimentation with the prior art would make it obvious to have the concentration as claimed.

9. The examiner would also like to note that there is a lack of criticality to the size of the dose of plasmin. There is no evidence in the specification that 0.4 IU is critical for the invention to work, and therefore the examiner determined that it would be obvious from the prior art references.

10. The examiner cites case law to further support his rejection based on the interpretations of optimization of ranges.

11. With regards to the optimization of ranges, the examiner would like to point out, that optimization within prior art conditions or through routine experimentation, generally, with differences in concentration or temperature will not support the patentability of subject matter

encompassed by the prior art unless there is evidence indicating such concentration or temperature is critical. "Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955), as well as a particular parameter must first be recognized as a result-effective variable, i.e., a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. In re Antonie, 559 F.2d 618, 195 USPQ 6 (CCPA 1977).

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 571-272-4957. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick LUCCHESI can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Matthew DeSanto
Art Unit 3763
March 16, 2005

NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700